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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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| 09/493,211 | 01/28/00 | APPELMELK | B 057666 |

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EXAMINER

KAM, C

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 03/14/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/493,211

Applicant(s)

APPELMELK ET AL.

Examiner

Chih-Min Kam

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claims 1-39 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U. S. C. 121:
 - I. Claims 1-13, 15-30, drawn to a peptide, a composition comprising the peptide, and a method of treating microbial infection using the peptide, classified in class 514, subclass 13, for example.

Claims 8-12 are further divided into 5 groups:

 1. Claim 8, drawn to the peptide having SEQ ID NO:1,
 2. Claim 9, drawn to the peptide having SEQ ID NO:2,
 3. Claim 10, drawn to the peptide having SEQ ID NO:3,
 4. Claim 11, drawn to the peptide having SEQ ID NO:4,
 5. Claim 12, drawn to the peptide having SEQ ID NO:5.

Should group I be elected, claims 1-7, 15-30 will be examined with one of the items I-1, I-2, I-3, I-4 or I-5.
 - II. Claim 14, drawn to a fusion protein, classified in class 435, subclass 69.7, for example.
 - III. Claims 31-34, drawn to a method of diagnosis using the peptide, classified in class 514, subclass 13, for example.
 - IV. Claims 35-36, drawn to a method of removal of endotoxin using the peptide, classified in class 514, subclass 13, for example.
 - V. Claims 37-39, drawn to a method of removal of lipopolysaccharide using the peptide, classified in class 514, subclass 13, for example.

2. The inventions are distinct, each from the other because of the following reasons:

The peptide of Invention I is related to the fusion protein of Invention II because the fusion protein contains the peptide which is coupled to a second peptide. The inventions are distinct because they are physically and functionally distinct chemical entities and the peptide can be made by chemical synthesis while the fusion protein can be made by recombinant techniques.

The product of Invention I and the methods of Inventions III-V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the peptide as claimed can be used in any method of Inventions III-V. The method of Invention I and Inventions III-V are alternative processes of use of the product of Invention I.

The product of Invention II is distinct from the method of Inventions I and III-V because the product of Invention II can be neither made by nor used in the Inventions I and III-V.

Inventions III-V are related because the Inventions use the product of Invention I. However, the method steps and outcomes are wholly different between Inventions III-V, therefore Inventions III-V are patently distinct.

In this instance Group I contains recitation of patentably distinct and/or independent peptide (I-1, I-2, I-3, I-4 or I-5). Each peptide has distinct and/or independent physical, chemical, and biological function. None would appear to be substitute for any one of the other

peptide. Thus, the claims are distinct and/or independent. Should Group I be elected, applicant is required under 35 U. S. C. 121 to select one of the peptide (I-1, I-2, I-3, I-4 or I-5).

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their recognized divergent subject matter, and because inventions I-V require different searches but are not co-extensive, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

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Chih-Min Kam, Ph. D.
Patent Examiner

March 9, 2001

Christopher S. F. Low
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SUPERVISORY PATENT EXAMINER
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